**216** 771 3804

01/23/06 16:51 1 :01/12 No:676

## D. PETER HOCHBERG CO., L.P.A

ATTORNEYS AT LAW

D. PETER HOCHBERG\* SEAN MELLINO KATHERINE R. VIEYRA

1940 EAST 6TH STREET - 6TH FLOOR CLEVELAND, OHIO 44114

INTELLECTUAL PROPERTY LAW

PATENT TRADEMARK AND COPYRIGHT LAW

TEL. (216) 771-3800 FAX. [216] 771-3804

JAMES A. RICH\*\*\* IAN M. SINGER\*\*\* OF COUNSEL

\* ALSO ADMITTED IN VIRGINIA AND NEW YORK \*\* ADMITTED IN VIRGINIA ONLY \*\*\* ADMITTED IN NEW YORK ONLY

January 23, 2006

e-mail: dphochberg@aol.com

Via fax only: 1 (571) 273-3201 – 12 pages

**PCT** Operations Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

Krumme U.S. Patent Appln. 10/533,835 filed May 4, 2005

MULTILAYERED TRANSMUCOSAL THERAPEUTIC SYSTEM

(per Preliminary Amendment on filing of application)

Our Ref. RO4037US (#90568)

#### Dear Sir or Madam:

Attached is a copy of the first page of the official Filing Receipt with a mailing date of 10/03/2005. Three portions of the Filing Receipt contain errors, namely: 1) the Applicant's city and state of residence is wrong, 2) the listing of attorneys under the section "Power of Attorney" is incomplete, and 3) the title should be as presented in the Preliminary Amendment filed with the application. The corrections are entered on the copy of the Filing Receipt and are noted below:

- Applicant: Markus Krumme, Randolph, New Jersey 1)
- Attorneys listed in the "Combined Declaration and Power of Attorney" at 2) page 3 (submitted herewith and discussed below):

D. Peter Hochberg Reg. No. 24,603 Sean Mellino Reg. No. 48,817 Katherine R. Vieyra Reg. No. 47,155 Reg. No. 25,519 James A. Rich

Title: MULTILAYERED TRANSMUCOSAL THEREPEUTIC SYSTEM 3)

Along with the official Filing Receipt, we received the Notice of Acceptance of Application that indicated: "Oath or Declaration filed on 05/04/2005." However, this was not the **PCT Operations** 

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January 23, 2006

Declaration and Power of Attorney that was executed by the inventor for this U.S. case. Accordingly, we are enclosing a copy of the "Combined Declaration and Power of Attorney" as executed by the applicant on May 19, 2005 for entry of the Power of Attorney portion of this document. Further, this Combined Declaration and Power of Attorney supports the inventor's address details, the attorney listing and the proper title for this case.

Heretofore, our procedure with our client was to obtain the inventor(s) signature(s) on a "Combined Declaration and Power of Attorney" and an "Assignment" for the individual national phase applications that we file for them, and subsequently file the Declaration and Power of Attorney when we received a Notice of Missing Requirements. Therefore, we were awaiting a Notice of Missing Requirements to formally submit the enclosed Declaration and Power of Attorney. However, we have learned that our client has been filing an Oath with their PCT applications that is being accepted by the USPTO; thus, no Notice of Missing Requirements is issued.

Further supporting the title for this application (MULTILAYERED TRANSMUCOSAL THERAPEUTIC SYSTEM) are copies of the first two relevant pages of the Preliminary Amendment as filed with the application. It appears that titles amended in a Preliminary Amendment are being overlooked when processing Filing Receipts for national phase applications.

Lastly, an "Application Data Sheet" is enclosed reflecting the proper details for this application. Correction of the records of the USPTO is respectfully requested, and we look forward to receiving a corrected Filing Receipt in due course.

Respectfully submitted,

D. Peter Hochberg

DPH/ck Enc. **216** 771 3804

01/23/06 16:51 1:03/12 NO:676 Page 1 of 3



### INITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addres: COMMISSIONER FOR PATENTS P.O. DOX: 1450 P.O. DOX: 1450

FILING OR 371 (c) DATE DRAWINGS TOT CLMS IND CLMS ART UNIT FIL FEE REC'D ATTY.DOCKET NO APPL NO. 22 2 1000 RO4037US (#90568) 10/533.835 05/04/2005

**CONFIRMATION NO. 8149** 

D Peter Hochberg 1940 East 6th Street 6th Floor Cleveland, OH 44114 FILING RECEIPT OC000000017129299\*

Date Mailed: 10/03/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)	Markus Krumme, Newied, GERMANY,	Should be;  Markus Krumme, Randolph, N	<u>vj 0786</u> 9
Power of Atto	<del>-</del>	D. Peter Hochberg Sean Mellino	Reg. No. 24,603 Reg. No. 48,817
Domestic Priority data as claimed by applicant		Katherine R. Vieyra James A. Rich	Reg. No. 47,155 Reg. No. 25,519
	This population is a 271 at U/ 1/EU/13/3	//// 11/DA//HIS	

Foreign Applications

GERMANY 10252726.1 11/13/2002

Projected Publication Date: 01/05/2006

Non-Publication Request: No

Early Publication Request: No

MULTILAYERED TRANSMUCOSAL THEREPEUTIC SYSTEM

Multi-layer transmucosal therapeutic system

Attorney Docket No. R04037US (#90568)

## COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)			
As a below named inventor, I hereby declare that:			
TYPE OF DECLARATION			
This declaration is of the following type: (check one applicable item below)			
( ) original ( ) design			
NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do <u>not</u> check any of next two items and check appropriate one of last three items.			
(X) national stage of PCT ( ) supplemental			
NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.			
<ul> <li>( ) divisional</li> <li>( ) continuation</li> <li>( ) continuation-in-part (CIP)</li> </ul>			
INVENTORSHIP IDENTIFICATION			
My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:			
TITLE OF INVENTION			
MULTILAYERED TRANSMUCOSAL THERAPEUTIC SYSTEM			
SPECIFICATION IDENTIFICATION			
the specification of which: (complete (a), (b), or (c))			

the specificat	tion (	of which: (complete (	a), (b), or (c))
(a)	(	) is attached hereto.	
(b)	(	) was filed on as (	) Serial Noo

			, as Serial No. not yet known
	and was amended on _	med in DCT Internations	(if applicable).
(c)	(X) was described and clai	2 filed on November 4 <sup>d</sup>	1 Application b 2003
		er PCT Article 19 on	
ACKN	OWLEDGEMENT OF RE	VIEW OF PAPERS AN	D DUTY OF CANDOR
I her specification.	eby state that I have reviewed including the claims, as amen	ed and understand the conded by any amendment r	ontents of the above-identified eferred to above.
I acks	nowledge the duty to disclose accordance with Title 37, Co	information which is ma de of Federal Regulations	terial to the examination of this s. Sec. 1.56(a).
( )	In compliance with this duty disclosure statement. 37 CF		rmation
	PRI	ORITY CLAIM	
foreign appli- designating a identified be international	cation(s) for patent or inventor t least one country other than clow any foreign application application(s) designating at least the same subject matter havi	or's certificate or of any F the United States of Ame a(s) for patent or invest east one country other that	ed States Code, Sec. 119 of any PCT international application(s) erica listed below and have also ntor's certificate or any PCT and the United States of America at of the application(s) of which
	(coi	mplete (d) or (e))	
	) no such applications have ${f X}$ ) such applications have bee		
NOTE: Who	ere item (c) is entered above priority check item (e), enter t	and the International Ap he details below and mak	plication which designated the te the priority claim.
EARI	LIEST FOREIGN APPLICAT (6 MONTHS FOR DESIGN		
COUNTRY	APPLICATION NO.	DATE OF FILING (month,day,year)	PRIORITY CLAIMED UNDER 37 USC 119
			( ) YES NO( )
			( ) VES NO( )

# ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Germany	Appln. 102 52 726.1	Filed November 13, 2002
PCT	Appln. PCT/EP 03/12272	Filed November 4 <sup>th</sup> , 2003

#### POWER OF ATTORNEY

As a named inventor, I hereby appoint D. Peter Hochberg, Reg. No. 24,603, Sean Mellino, Reg. No. 48,817, Katherine R. Vieyra, Reg. No. 47,155, and James A. Rich, Reg. No. 25,519, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

SEND CORRESPONDENCE TO:

DIRECT TELEPHONE CALLS TO: (Name and telephone number)

D. Peter Hochberg Co., L.P.A. The Baker Building - 6th Floor 1940 East 6th Street Cleveland, Ohio 44114-2294

D. Peter Hochberg (216) 771-3800

#### **DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

#### SIGNATURE(S)

Full name of sole inventor: Markus KRUMME		
holm brumme		
Inventor's signature		
5/19/205	Germany	
Date	Country of Citizenship	
9 Rose Way, Randolph, NJ 07869, USA		
Residence		
9 Rose Way, Randolph, NJ 07869, USA		
Post Office Address		

#### CHECK PROPER BOX(ES) IF ANY OF THE FOLLOWING ADDED PAGE(S) FORM A PART OF THIS DECLARATION

(	)	pages added
(	)	Signature by administrator(trix), executor(trix) or legal representative of deceased or incapacitated inventor. Number
		of pages added
(	)	Signature for inventor who refuses to sign or cannot be reached
•	•	by person authorized under 37 CFR 1.47. Number of pages added
		•
		***
(	)	Added pages to combined declaration and power of attorney for a conversion of a provisional, divisional, continuation, or continuation-in-part (CIP)
		application. (Not required if modifications for provisional incorporated herein.)
,	`	Number of pages added
(	)	Number of pages added

If no further pages form a part of this Declaration then end this Declaration with this page and check the following item.

(X) This declaration ends with this page.

#### **EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10**

I hereby certify that the paper(s) identified above, and any document(s) referred to as attached hereto, is being deposited with the United States Postal Service on the date indicated in an envelope as "Express Mail Post Office to Addressee" and is addressed: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450.

Christine Kotran

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Markus Krumme

Serial No.

Filing Date

Herewith

Examiner

Group Art Unit:

Title

MULTILAYERED TRANSMUCOSAL THERAPEUTIC

SYSTEM (as amended herein)

Attorney File:

RO4037US (#90568)

Mail Stop PCT Commissioner for Patents P.O. Box 1450 Alexandria, Virginia, 22313-1450

#### PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-referenced application as follows:

D PETER HOCHBERG CO LPA

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01/23/06 16:51 ☐ :09/12 NO:676

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In the Title:

Please amend the title of the application from "MULTI-LAYER TRANSMUCOSAL THERAPEUTIC SYSTEM" to "MULTILAYERED TRANSMUCOSAL THERAPEUTIC SYSTEM."

Date: January 23,2006

## **CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below:

To Fax No.: 1 (571) 273-3201

Va -

Christine A. Kotran

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Markus Krumme

Serial No.:

10/533,835

Filed:

May 4, 2005 / Conf. No. 8149

Title:

MULTILAYERED TRANSMUCOSAL THERAPEUTIC SYSTEM

Art Unit:

1616

Attorney File:

RO4037US (#90568)

PCT Operations Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### APPLICATION DATA SHEET

1. Applicant Information (including name, residence, mailing address and citizenship):

Markus Krumme

a citizen of Germany

9 Rose Way

Randolph, NJ 07869, U.S.A.

2. Correspondence Information:

D. Peter Hochberg, Esq. D. Peter Hochberg Co., L.P.A. 1940 East 6<sup>th</sup> Street – 6<sup>th</sup> Floor

Cleveland, Ohio 44114

Phone: (216) 771-3800 / Fax: (216) 771-3804

Email: dphdocket@aol.com

Customer No. 28,672

## 3. Application Information:

Title:

MULTILAYERED TRANSMUCOSAL THERAPEUTIC SYSTEM

1

1

Total number of drawing sheets:

Suggested drawing figure for publication:

Docket number assigned to application: RO4037US (#90568)

Type of application (e.g., utility, plant, design, reissue, provisional): Utility

Any significant part of application subject matter subject to secrecy order: No

4. Representative Information (including Reg. No. of each practitioner having Power of Atty.):

D. Peter Hochberg Reg. No. 24,603
Sean Mellino Reg. No. 48,817
Katherine R. Vieyra Reg. No. 47,155
James A. Rich Reg. No. 25,519

D. Peter Hochberg Co., L.P.A. 1940 East 6<sup>th</sup> Street – 6<sup>th</sup> Floor Cleveland, Ohio 44114

Phone: (216) 771-3800 / Fax: (216) 771-3804

Email: dphdocket@aol.com

Customer No. 28,672

5. <u>Domestic Priority Information (including appln. no., filing date, status - including patent</u> number if available - and relationship of each appln. for which a benefit is claimed):

Not applicable.

6. Foreign Priority Information (including appln. no., country and filing date of each foreign appln. for which priority is claimed, as well as any foreign appln. having a filing date before that of the appln. for which priority is claimed):

U.S. national phase of PCT/EP03/012272 filed November 4, 2003

Claims priority of German Appln. No. 102 52 726.1 filed November 13, 2002

7. Assignee Information (including name – either person or juristic entity – and address of the assignee of the entire right, title and interest in an appln.):

LTS Lohmann Therapie-Systeme AG Lohmannstrasse 2 Andernach, Germany 56626

Respectfully submitted,

DPH/ck

D. Peter Hochberg Reg. No. 24,603

D. Peter Hochberg Co., L.P.A. 1940 E. 6th Street - 6<sup>TH</sup> Floor Cleveland, Ohio 44114 Phone: (216) 771-3800 Fax: (216) 771-3804

e-mail: dphdocket@aol.com